



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Atsutoshi IKESUE et al.

Group Art Unit: 3761

Application No.: 10/557,611

Examiner: Not Yet Assigned

Filed: November 22, 2005

Attorney Docket No.: 7388/84495

Confirmation No.: 1480

Customer No.: 42798

**SUBMISSION OF ENGLISH TRANSLATION OF  
INTERNATIONAL PRELIMINARY REPORT**

Commissioner for Patents  
Customer Service Window  
Randolph Building  
401 Dulany Street  
Alexandria, VA 22314

Sir:

Applicants submit herewith an English translation of the International Preliminary Report on Patentability (Chapter I) for the above-captioned application.

Respectfully submitted,

FITCH, EVEN, TABIN & FLANNERY

Kendrew H. Colton  
Registration No. 30,368

Date: **December 4, 2006**

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From the INTERNATIONAL BUREAU

**PCT**

NOTIFICATION OF TRANSMITTAL  
OF COPIES OF TRANSLATION  
OF THE INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY  
(CHAPTER I OR CHAPTER II  
OF THE PATENT COOPERATION TREATY)  
(PCT Rules 44bis, 3tc) and 72.2)

To:

Date of mailing (day/month/year)  
23 March 2006 (23.03.2006)

Applicant's or agent's file reference  
FP04-0130-00

International application No.  
PCT/JP2004/007403

International filing date (day/month/year)  
24 May 2004 (24.05.2004)

Applicant  
HISAMITSU PHARMACEUTICAL CO., INC. et al

**IMPORTANT NOTIFICATION****1. Transmittal of the translation to the applicant.**

The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter I).



The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter II).

**2. Transmittal of the copy of the translation to the designated or elected Offices.**

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following designated or elected Offices requiring such translation:

None

The following designated or elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

AE, AG, AL, AM, AP, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EA, EC, EE, EG, EP, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OA, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW

**3. Reminder regarding translation into (one of) the official language(s) of the elected Office(s).**

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability (Chapter II).

It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned within the applicable time limit (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.

The International Bureau of WIPO  
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# PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference FP04-0130-00	<b>FOR FURTHER ACTION</b>	See item 4 below
International application No. PCT/JP2004/007403	International filing date ( <i>day/month/year</i> ) 24 May 2004 (24.05.2004)	Priority date ( <i>day/month/year</i> ) 23 May 2003 (23.05.2003)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant HISAMITSU PHARMACEUTICAL CO., INC.		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

- |                                     |              |   |
|-------------------------------------|--------------|---|
| <input checked="" type="checkbox"/> | Box No. I    | Basis of the report   |
| <input type="checkbox"/>            | Box No. II   | Priority  |
| <input checked="" type="checkbox"/> | Box No. III  | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability  |
| <input type="checkbox"/>            | Box No. IV   | Lack of unity of invention  |
| <input checked="" type="checkbox"/> | Box No. V    | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/>            | Box No. VI   | Certain documents cited   |
| <input type="checkbox"/>            | Box No. VII  | Certain defects in the international application  |
| <input type="checkbox"/>            | Box No. VIII | Certain observations on the international application   |

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Date of issuance of this report 16 March 2006 (16.03.2006)
Facsimile No. +41 22 740 14 35	Authorized officer  <div style="text-align: center; font-weight: bold;">Yoshiko Kuwahara</div>
Telephone No. +41 22 338 90 90	

# PATENT COOPERATION TREATY

Translation

From the  
INTERNATIONAL SEARCHING AUTHORITY

## PCT

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To:

Date of mailing  
(day/month/year)

Applicant's or agent's file reference

**FP04-0130-00**

**FOR FURTHER ACTION**

See paragraph 2 below

International application No.

**PCT/JP2004/007403**

International filing date (day/month/year)

**24.05.2004**

Priority date (day/month/year)

**23.05.2003**

International Patent Classification (IPC) or both national classification and IPC

Applicant

**HISAMITSU PHARMACEUTICAL CO., INC.**

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/JP

Authorized officer

Facsimile No.

Telephone No.

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2004/007403

Box No. 1

Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.  
☐ This opinion has been established on the basis of a translation from the original language into the following language  
\_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
  - a. type of material  
☐ a sequence listing  
☐ table(s) related to the sequence listing
  - b. format of material  
☐ in written format  
☐ in computer readable form
  - c. time of filing/furnishing  
☐ contained in the international application as filed.  
☐ filed together with the international application in computer readable form.  
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2004/007403

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 12

because:

☒ the said international application, or the said claims Nos. 12  
relate to the following subject matter which does not require an international preliminary examination (*specify*):

Claim 12 pertains to methods of treatment of the human body by therapy.

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. \_\_\_\_\_  
are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. \_\_\_\_\_ are so inadequately supported  
by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 12

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details.

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2004/007403

Box No. V	Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability: citations and explanations supporting such statement		
1. Statement			
Novelty (N)	Claims	1-11, 13	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1-11, 13	NO
Industrial applicability (IA)	Claims	1-11, 13	YES
	Claims		NO
2. Citations and explanations:			
<p>The following documents are listed in the ISR.</p> <p>Document 1/IP 9-169658 A  Document 2/IP 2002-104922 A  Document 3/EP 1146111 A1  Document 4/WO 2002/102376 A1  Document 5/FLAVOUR AND FRAGRANCE JOURNAL, 2002, Vol. 17, Number 5, page 380-384.  Document 6/Journal of Essential Oil Research, 1993, Vol. 5, Number 2, page 153-158.  Document 7/IP 8-283150 A  Document 8/Bioorganic &amp; Medicinal Chemistry, September 2003, Vol. 11, Number 19, page 4207-4216.  Document 9/Journal of Dental Research, 1986, Vol. 65, Number 1, page 53-56.  Document 10/Seikagaku Jiten, Dai 3 ban, Tokyo Kagaku Dozin, 1998, p. 233</p> <p>(1) Inventive Step of Claims 1-4, 10, 11, and 13/Documents 1-6  Document 1 describes that ketoprofen and other nonsteroidal anti-inflammatory drugs cause photosensitivity. (See paragraphs 0002-0003 and 0009, etc., in particular.)  Document 3 describes that free radical scavengers can be added to dermatologic agents in order to prevent photosensitivity. (See paragraphs 0010-0028, etc., in particular.)  In addition, relating to free radical scavengers, documents 3 and 4 describe gallic acid propyl ester and other gallic acid alkyl esters, di-tert-butyl-hydroxy toluene, and di-tert-butyl-hydroxy anisole, as free radical agents, and documents 5 and 6 describe thymol as a free radical scavenger. (See paragraph 0108 in document 3; page 18, line 8-page 18, line 20 in document 4; page 384, table 2 in document 5; page 157, table 3 in document 6, etc., in particular.)  Consequently, the addition and joint use of free radical scavengers described in documents 3-6 in production of dermatologic agents containing a nonsteroidal anti-inflammatory drug are obvious to a person skilled in the art, keeping in mind the descriptions in documents 1 and 2.</p>			
(Continued)			

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of Box V:

Also, in terms of photosensitivity suppressive effect described in the specification, keeping in mind embodiments and comparative examples, increasing the distributed amount of material possessing free radical scavenging activity does not exceed the expected range of a person skilled in the art.

(2) Inventive Step of Claims 5-9/Documents 7-10

Document 7 describes the anti-inflammatory action of gallic acid alkyl esters such as gallic acid propyl.

Document 8 describes the lipoxygenase inhibitory activity relating to anti-inflammatory action of di-tert-butyl-hydroxy toluene and di-tert-butyl-hydroxy anisole. (See page table 1 on 4209 and table 2 on page 4210, etc., in particular.)

Document 9 describes the anti-inflammatory action of thymol. (See Fig. 1, table 1 on page 54, etc., in particular.)

As described in document 10, in terms of participation of interleukin 1 in the occurrence of inflammation, in order to elucidate the mechanism anti-inflammation action of gallic acid alkyl ester, di-tert-butyl-hydroxy toluene, di-tert-butyl-hydroxy anisole, thymol, and the like, measuring the interleukin-1 $\alpha$  production suppressive action of these compounds is merely an obvious matter for a person skilled in the art.